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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,152	09/25/2006	Xin-Yun Huang	2003080-0205 (SK-1071-US2)	4442
63411 7590 10/19/2010 CHOATE, HALL & STEWART LLP/MSKCC SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH TWO INTERNATIONAL PLACE BOSTON, MA 02110			EXAMINER HAVLIN, ROBERT H	
			ART UNIT 1626	PAPER NUMBER
			NOTIFICATION DATE 10/19/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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lbradley@choate.com

<b>Office Action Summary</b>	Application No. 10/551,152	Applicant(s) HUANG ET AL.	
	Examiner ROBERT HAVLIN	Art Unit 1626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14, 16-20, 28-31, 41, 42 and 45-47 is/are pending in the application.
- 4a) Of the above claim(s) 28, 29 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14, 16-20, 27, 30, 41, 42 and 45-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/2/10</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

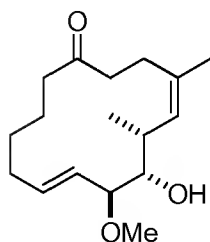
**Status of the claims:** Claims 1-12, 14, 16-20, 28-31, 41-42 and 45-47 are currently pending.

**Priority:** This application is a 371 of PCT/US04/09380 (03/26/2004) which claims benefit of 60/458,827 (03/28/2003) and claims benefit of 60/496,165 (08/19/2003).

**RCE:** A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/2/10 has been entered.

### *Election/Restrictions*

1. Applicant previously elected the following species (stated to read on claims 1-12, 14, 16-20, 30, 41-42, 45-47):



As detailed in the following rejections, the generic claim encompassing the elected species was not found patentable. Therefore, the provisional election of species is given effect, the examination is restricted to the elected species only, and

claims not reading on the elected species are held withdrawn. Accordingly, claims 28, 29, 31 are hereby withdrawn.

Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection through amendment, the amended Markush-type claim will be reexamined to the extent necessary to determine patentability of the Markush-type claim. See MPEP § 803.02.

### **RESPONSE TO APPLICANT REMARKS**

#### ***Claim Rejections - 35 USC § 112***

2. Claims 1-12, 14, 16-20, 30, 41-42, 45-47 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds identified as having activity through relevant experimental data, does not reasonably provide enablement for the asserted utility of the entirety of the claim scope, in particular for treating tumor metastases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant argues that the experimentation required to test the utility of the compounds of the claim scope would be routine and not undue. Even if one of skill in the art were to implement the high-throughput screening methods applicant describes (working in parallel at ~100 compounds simultaneously screened), this would still be a burden even if each assay required only one hour for processing – i.e.  $356 \times 24 \times 100 > 1$  year / 1 million compounds. In addition, this analysis does not take into account the often burdensome process of actually synthesizing the 100 compounds per hour

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required as input into the assay. Therefore, applicant's argument that the burden is not undue is not persuasive and the rejection is **maintained**.

### **NEW REJECTIONS**

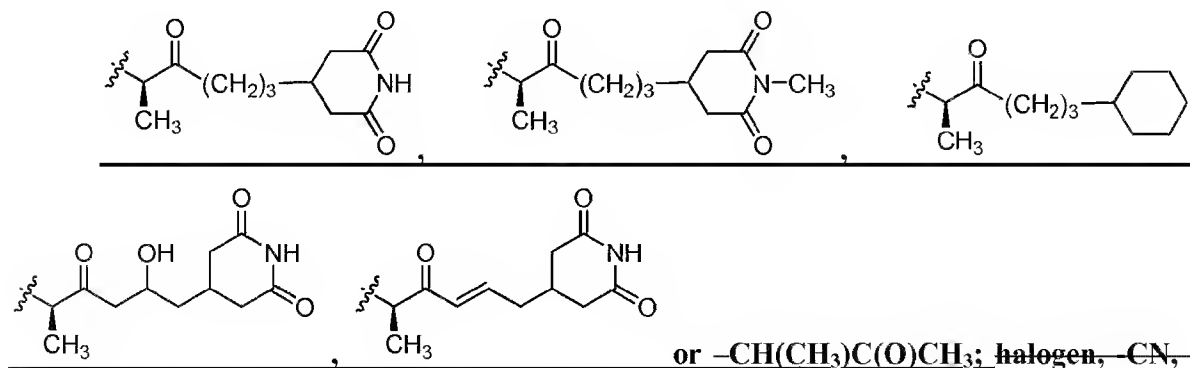
#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 1 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims amendments of 12/5/08 contained amendments that are not supported by the original claims or the specification. In particular, the variable Q lists the following new alternatives:



without specific support in the claims or specification, nor are there sufficient representative species to support this new subgenus.

***Claim Rejections - 35 USC § 102***

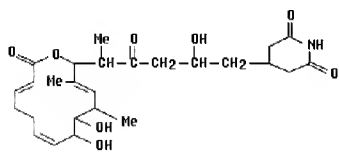
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-12, 14, 16-20, 30, and 41-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Isogai et al. (STN Abstract of JP 07138257 A).

The prior art reference teaches the following compound as a bone absorption inhibitor:

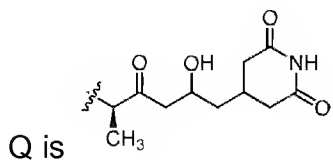


which reads on the instant claims when:

R1, R2, R3, Ra, Rb, Rc are H

R4 is –OH

R5, R6 are –Me



X1 is –O–

C(Y1)(Y2) form –C(O)–.

***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-12, 14, 16-20, 30, 41-42, 45-47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 112 of co-pending application No. 10/551158. Although the conflicting claims are not

identical, they are not patentably distinct from each other because the claims of the '158 application anticipate the instant claims.

This is a provisional rejection because the claims have not yet issued.

### ***Conclusion***

The claims are not in condition for allowance.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is (571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.



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Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/  
Examiner, Art Unit 1626